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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/014,750 | 10/25/2001 | Jenny Louie-Helm | 3100-0003 | 1055 |

23980 7590 01/27/2005

REED INTELLECTUAL PROPERTY LAW GROUP
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| EXAMINER | |
|---|---|
| FUBARA, BLESSING M | |
| **ART UNIT** | **PAPER NUMBER** |
| 1615 | |

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/014,750 | LOUIE-HELM ET AL. | |
| | Examiner | Art Unit | |
| | Blessing M. Fubara | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-37,39,40 and 45-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37, 39, 40 and 45-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 08/26/04. Claims 1-37, 39, 40 and 45-54 are pending.

The suggestion that the term "cellulosic" be changed to cellulose is withdrawn in light of applicants' argument.

### *Claim Rejections - 35 USC § 102*

1. Claims 1-9, 12-16, 18-23, 26-34, 36, 37, 39, 40 and 45-54 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shell et al. (US 5,972,389).

2. Claims 1-7, 10, 12, 17-23 and 45-49 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shell (US 5,007,790).

3. Claims 1-7, 10, 17-22 and 39 remain rejected under 35 U.S.C. 102(b) as being anticipated by Uemura et al. (US 4,695,467).

**Applicants argue for product-by-process**. "Wherein the dosage form is optimized by subjecting the dosage form to disintegration test for an extended period of time such that the dosage form has an in vivo active agent release profile that correlates to the desired in vivo active agent release profile for the dosage form" is not a process of preparing the dosage form. The cited phrase talks of optimizing the dosage form and there is no recitation that the "dosage form is prepared by the process of disintegration..." as stated by the applicants. Even if claim 1 were a product-by-process claim, it is noted that MPEP 2113 [R-1] states that "PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS." And "[e]ven though product-by-process claims are limited by and defined by the process, determination of

patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case the product in claim 1 is a dosage form and there is no structural difference between the dosage form of the prior art and the instant dosage form. No structure is implied by "wherein the dosage form is optimized by subjecting the dosage form to disintegration test for an extended period of time such that the dosage form has an in vivo active agent release profile that correlates to the desired in vivo active agent release profile for the dosage form."

Applicants traverse the above rejections on the ground that the prior art does not disclose the "use of a disintegration test to optimize the dosage form," which according to applicants is a structural element.

4. Applicants' arguments filed 08/26/04 have been fully considered but they are not persuasive. "Wherein the dosage form is optimized by subjecting the dosage form to disintegration test for an extended period of time such that the dosage form has an in vivo active agent release profile that correlates to the desired in vivo active agent release profile for the dosage form" does not produce a structurally different dosage form from the dosage form of the prior art and as noted above, product by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. Specifically, claim 1 is not a product by process step. Also, "patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different

process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). (MPEP 2113 [R-1].

5. Claims 1, 6-8, 10, 11, 23-25, 30, 34 and 35 remain rejected under 35 U.S.C. 102(e) as being anticipated by Vandecruys et al. (US 6,667,069).

Applicants argue that Vandecruys does not disclose all the elements of the claims expressly or inherently.

6. Applicants' arguments filed 08/26/04 have been fully considered but they are not persuasive.

Vandecruys discloses all the elements of the claims by disclosing a controlled release matrix formulation that comprises xanthan gum, hydroxypropylmethyl cellulose or polyethylene oxide in the matrix (abstract, column 9, line 19 and 31) and metformin antidiabetic agent (column 5, line 65), topiramate anti-epileptic drug (column 6, line 2) or paclitaxel (column 6, line 19) as some of the active agent in the matrix. Xanthan gum is a swellable polymer. Metformin antidiabetic agent is a pharmacologically active agent. Swelling in the presence of water is a property of the dosage form and a dosage form as broadly claimed as that in claim 1 will swell in water. Item 6 does not produce a dosage form that is structurally different from that of the prior art.

No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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